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10/577,977	05/03/2006	Michael Birsha Davies	PB60512USW	7528

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EXAMINER	
STUART, COLIN W	

ART UNIT	PAPER NUMBER
3771	

NOTIFICATION DATE	DELIVERY MODE
09/18/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,977	DAVIES ET AL.	
	Examiner	Art Unit	
	COLIN STUART	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 May 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/3/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is in response to the preliminary amendment filed 5/3/06. As directed by the amendment no claims have been added, and claim 55 has been cancelled. Currently, claims 1-54 are pending in the instant application.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the follower element, force modifying means, cam, stop element, screw, and gradient profiles must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "28" in Fig. 2a has been used to designate both the step and the pre-load means and reference characters "20" and "21" in Fig. 1 have been used to designate both the levers and the finger operable means.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for

consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Information Disclosure Statement

3. The information disclosure statement filed 5/3/06 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

In regards to the crossed out reference JP-09225363, it appears that no English translated abstract has been provided. However, the reference number for this document appears in the English translated abstract for JP-09313998.

In regards to the crossed out reference FR-2671294, no English translated abstract and/or full document has been submitted.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-54 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claims 1 and 54, the language “finger operable means” and "pre-load means" is unclear because it appears the applicant is trying to invoke 35 USC 112 6th paragraph. However, the language doesn't not meet the 6th paragraph standard as it doesn't follow the 'means for + function'. Also the language “preload means” is unclear because the examiner cannot ascertain what structure present in the claims is providing a ‘pre-load’ to the device.

In regards to claim 5, the language "the or each lever" in lines 1-2 is unclear lacks antecedent basis because only one lever has been positively recited in the previous claims.

In regards to claim 47, the language “from 20 to 100 mPa.s, preferably from 50 to 1000 mPa.s at 25 degree C” in lines 2-3 is unclear because this is a range within a range.

Claims 2-4, 6-46, and 48-53 are rejected due to dependency on a rejected claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Davies (2005/0224525)

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

In regards to claims 1 and 54, Davies shows a fluid dispensing device, which is a kit of parts, which includes a housing 9, a nozzle 11 for insertion into a body cavity, a fluid discharge device 8 moveably housed within the housing having a longitudinal axis and including a container 30 containing fluid medicament, a compression pump (see Figs. 1 & 3), having a suction inlet located within the container at an opening of a discharge tube 31 extending along the longitudinal axis for transferring fluid. The Davies device also includes a finger operable means 20 & 21 moveable with respect to the longitudinal axis to apply a force to move the container along the longitudinal axis and a pre-load means 28 (see Figs. 1 & 2a) provided to prevent actuation of the pump until a pre-determined force is applied. The Davies device has all the structure present

as the claimed invention and is able to be used with a medicament formulation with a viscosity of from 10 to 2000 mPa.s at 25 degrees C.

In regards to claims 2-8 and 18, the Davies device includes at least one lever to apply force to an actuating means (122a) and furthermore, includes two opposing levers (see Fig. 1). The or each lever are pivotally supported at a lower end within the housing and urge the container towards the nozzle when squeezed with the pre-load means interposed between the finger operable means and the container or housing (see Fig 1).

In regards to claims 9-10, the Davies device includes a pre-load means in the form of a step (28 Fig. 2a) which must be ridden over by the finger operable means to actuate the device when pre-determined pressure is applied.

In regards to claim 11, the Davies device includes at least one detent 29 formed on one of the container or finger operable means and a recess 27 on the other wherein the detent rides out of the recess when pre-determined force is applied (see Fig. 2b).

In regards to claims 12-15, the Davies device also includes a pre-load means interposed between the housing and the container or discharge tube. The pre-load means including one or more detents formed on the container or housing and disengageable when the pre-determined force is applied (see Figs. 6-8).

In regards to claims 16-17, Davies device includes a step formed on the discharge tube and at least one latching member attached to the container (see Figs. 6-8) for actuating the device when the pre-determined force is present. It also includes a recess on the discharge tube (see Figs. 6-8).

In regards to claims 19-21, Davies device includes at least one detent on either the housing or finger operable means, disengageable when the pre-determined force is present and pre-load means between the housing and actuating means.

In regards to claims 22-26, Davies device includes, as discussed above, at least one detent on the housing or actuating means or lever, and pre-load means between the finger operable means and actuating means for actuating the device when the pre-determined force is applied.

In regards to claims 27-33, the Davies device has all the structure of the claimed invention and therefore has a variable mechanical ratio and two-stage gradient profiles as claimed. It also includes a fitting, or collar, 43 (Fig. 7) with a follower element.

In regards to claim 34-35, the Davies device includes a single lever 170 and a spring 176 interposed between the lever and container as claimed (see Fig. 11). The spring is compressed by lever until pre-determined force is applied to prevent accidental actuation.

In regards to claim 36-45, the Davies device includes an integral force modifying means in the form of the shape of the finger operable means or levers (see Fig. 1). It contains the same structure as the claimed invention and is able to amplify the force in a uniform manner in a degree of amplification from 1.5 to 10. The force modifying means acts constantly once the pre-determined force as been applied.

In regards to claim 46, the Davies device includes a stop element in the form of the shape of the housing which restricts or stops the axial movement of the container along the longitudinal axis (see Figs. 1 & 3).

In regards to claim 47-53, the Davies device includes the exact same structure as the claimed invention (see all Figs.); therefore, it is able to be used with the claimed medicament formulation, including the varying viscosities, type of medicament, and additional medical compounds in the medicament as claimed.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 1-10, 12, 15, 18, 21, 24, 27-28, 30-33, 36-48 and 54 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Simon et al. (WO 03/029105) in view of Grychowski et al. (6,745,760).

In regards to claims 1 and 54, Simon teaches a fluid dispensing device, which is a kit of parts, that includes a housing 30, a nozzle 31 for insertion into the body cavity, a fluid discharge device with a longitudinal axis including a container 10, a compression pump 20 and finger operable means 50 to apply a force to the container to move along the longitudinal axis towards to the nozzle to actuate the pump. The Simon device also includes a pre-load means 11 which is the shape of the finger operable means which prevents actuation until a sufficient pre-determined force is applied to the finger operable means. Although the Simon reference is silent as to the device including a discharge tube and suction inlet, these features must be present for the fluid medicament to actually be discharged to the user through the nozzle. Therefore, it is inherently that Simon has the claimed discharge tube and the suction inlet. Even if Simon does not show explicitly show or mention the discharge tube and suction inlet, Grychowski teaches a fluid discharge device which includes a discharge tube (Grychowski 16 Fig. 13) which inherently has a suction inlet. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the Simon device to include a discharge tube and suction inlet as taught by Grychowski in order to provide a conduit in which the fluid medicament can escape the container and be discharge to the user through the nozzle. Furthermore, the now modified Simon's device is capable of using a fluid medicament with the claimed viscosity of from 10 to 2000 mPa.s at 25 degrees C.

In regards to claims 2-4, the modified Simon's device includes at least one lever, and addition includes two opposing levers (50 Simon) pivotally connected to the

housing and acts upon the container to urge it towards the nozzle when squeezed. The levers apply a force to the container towards the nozzle to activate the compression pump. This action is the actuating means as claimed.

In regards to claims 5-7, the modified Simon's device has two opposing levers pivotally supported at a lower end of the housing and actuating means connected to the neck of the container (see Simon Fig. 1). The levers are slidably supported within the housing as they slide over the back end of the container to actuate the device (see Figs. 1-2).

In regards to claims 8-9 and 18, the modified Simon's device includes pre-load means interposed between the finger operable means and the container or housing as discussed above and includes a step formed on the container (the outside corner of the container; see Simon Figs. 1-2) which must be ridden over by the finger operable means to actuate the compression pump when the pre-determined amount of force is applied.

In regards to claim 10, the modified Simon's device includes a step shape (45 Simon) to the finger operable means which must be ridden over by the container to actuate the compression pump when the pre-determined amount of force is applied (see Simon Figs. 1-2).

In regards to claims 12 and 15, the modified Simon's device includes preload means which are disposed between the housing and the container, and also between the container and the discharge tube, in the form of the force it takes to axial move the container towards the nozzle and activate the compression pump.

In regards to claim 21, the modified Simon's device includes pre-load means as discussed above, which is located between the actuating means and the housing (see Simon Figs. 1-2).

In regards to claim 24, the modified Simon's device includes pre-load means as discussed above, which is located between the actuating means and the finger operable means (see Simon Figs. 1-2).

In regards to claims 27-28, the modified Simon's device includes the same structure as the claimed invention; therefore, the modified Simon's device includes pre-load means which defines a variable mechanical ratio such that until the pre-determined force is applied, no significant force is transferred to the container. The ratio is defined by the profile of interaction between a surface of the finger operable means with a follower element (see Simon Figs. 1-2) provided to the container or a fitting.

In regards to claims 30-33, the modified Simon's device includes the same structure as the claimed invention. Therefore the Simon's device has a variable mechanical ratio which includes a high gradient and lower gradient profile which can be either liner, curved with smooth break point, or part-circle forms as claimed.

In regards to claim 36, the modified Simon's device includes force modifying means which is the shape of the actuating means or step (see Simon 45 Figs. 1-2) which modify the force applied to the container by the finger operable means.

In regards to claims 37-41, the modified Simon's device contains the same structure as the claimed invention. Therefore, the force modifying means, integral with the finger operable means and between the finger operable means and the container, of

the modified Simon's device amplifies the force applied to the container by the finger modifying means in a uniform manner and to a degree of amplification from 1.5 to 10.

In regards to claim 42-45, the modified Simon's device includes force modifying means in the form of a lever with a cam surface (see Simon Figs. 1-2) and acts in an increasing relatively constant manner, once a pre-determined force is applied to the finger operable means.

In regards to claim 46, the modified Simon's device includes a stop element in the form of the inside top part of the housing which prevents the container from moving further along the longitudinal axis than desired (see Simon Figs. 1-2).

In regards to claims 47-48, the modified Simon's device includes all the same structure as the claimed invention. Therefore, it is capable of using liquid medicament solution formulation which has a viscosity from 20-100 mPa.s and preferably from 50-1000 mPa.s at 25 degrees C.

9. Claims 16-17, 29, and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (WO 03/029105) as applied to claim 1 above, and further in view of Grychowski et al. (6,745,760).

In regards to claims 16-17, the modified Simon's device is silent as to providing a step or recess on the discharge tube and at least one latching member attached to the container. However, Grychowski teaches a fluid dispensing device which includes a step or recess on the discharge tube (step 605 or recess 610 see Grychowski Fig. 47) and at least one latching member (608 see Grychowski Fig. 47) attached to the

container such that when the pre-determined force is applied to the finger operable means the latching member rides over the step to cause activation of the compression pump. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Simon's device to include the step connected to the discharge tube as taught by Grychowski and latching member in order to provide a more accurate and controlled method of activation.

In regards to claim 29, the modified Simon's device is silent as to providing a fitting which includes a collar. However, the Grychowski device includes a collar (Grychowski 7 see Fig. 47). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Simon's device to include a collar as taught by Grychowski in order to provide an extra element to assist in the actuation of the device.

In regards to claims 34-35, the modified Simon's device uses two levers instead of a single lever with a spring interposed between the lever and the container to urge the container towards the nozzle to activate the device. However, Grychowski teaches a fluid discharge device which includes a single lever (Grychowski 102 see Fig. 45) and a spring (Grychowski 530 see Fig. 45). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Simon's device to replace the two opposing levers with a single lever and spring as taught by Grychowski in order to reduce the number of parts and the difficulty of assembly. The now modified Simon's device's spring is compressed by movement of the lever until a

pre-determined force is applied which then actuates the compression pump by moving the container towards to nozzle.

10. Claims 11, 13-14, 19-20, 22-23, and 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (WO 03/029105) and Grychowski et al. (6,745,760) as applied to claims 21, 24, 8, 12, or 18 above, and further in view of Gueret (4,807,786).

In regards to claim 11, the modified Simon's device includes all the limitations as discussed above, but is silent as to providing at least one detent on one of the container or finger operable means and a recess on the other of the two. However, Gueret teaches a fluid canister which includes a detent 214 on a cap with finger operable means which is engaged with a part of the housing (see Gueret Figs. 7-8) and a recess (Gueret 223 see Fig. 8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Simon's device to include a detent on the container or finger operable means and a recess as taught by Gueret in order to provide an extra element for preventing unintended actuation of the device.

In regards to claims 13-14, the modified Simon's device includes a detent as discussed above. Furthermore, the location of the detent on the container or housing and the recess on the housing or container respectively and vice versa is considered to be an obvious matter of design choice as one of ordinary skill in the art would expect the device to perform equally as well.

In regards to claims 19-20, as discussed above, the modified Simon's device includes a detent and a recess, and placement of the detent on either housing or finger operable means and recess on the finger operable means or the housing respectively and vice versa would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made.

In regards to claim 22, the modified Simon's device includes all the limitations as discussed above, but is silent as to providing at least one detent formed on part of the actuating means for engagement with part of the housing, the or all the detents being disengagable from the housing when the pre-determined force is applied. However, Gueret teaches a fluid canister which includes a detent 214 on a cap with actuating means which is engaged with a part of the housing (see Gueret Figs. 7-8). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified Simon's device to include a detent on the actuating means as taught by Gueret in order to provide an extra element for preventing unintended actuation of the device.

In regards to claim 23, the now modified Simon's device includes a detent as discussed above, however with the detent located on the actuating means as opposed to the housing and includes a recess (Gueret 223 see Fig. 8). However, one of ordinary skill in the art at the time the invention was made would have found this to be an obvious matter of design choice to place the detent on the housing and the recess on the actuating means as exchanging male-female type connections is an obvious design choice and one would expect the device to perform equally as well.

In regards to claims 25-26, as discussed above, the modified Simon's device includes a detent and a recess and placement of the detent and recess on either the each lever and actuating means respectively and vice versa would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made.

11. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (WO 03/029105) and Grychowski et al. (6,745,760) as applied to claim 47 above, and further in view of Byron et al. (5,190,029).

In regards to claim 49, the modified Simon's device is silent as to being used with a suspension formulation including suspension of active medicament particles in an inert suspending formulation. However, because Simon's device contains the same structure as claimed, it is capable of using this type of medicament. Furthermore, Byron teaches a formulation for delivery of drugs by aerosol means which includes using a suspension formulation as claimed (see Byron col. 5 ln. 31-21). It would have been a matter of obvious design choice to one of ordinary skill in the art at the time the invention was made to use a suspension formulation as taught by Byron as one would expect the device to perform equally well with the claimed suspension formulation.

12. Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simon et al. (WO 03/029105) and Grychowski et al. (6,745,760) as applied to claim 47 above, and further in view of Rand et al. (6,568,389).

In regards to claim 50, the modified Simon's device teaches all the limitations as discussed above, but is silent as to providing that the medicament formulation including anti-inflammatory compounds. However, because Simon's device contains the same structure as claimed, it is capable of using this type of medicament. Furthermore, Rand teaches a fluid delivery device which includes using anti-inflammatory compounds in the medicament (see Rand col. 8 ln. 59). It would have been a matter of obvious design choice to one of ordinary skill in the art at the time the invention was made to use a formulation including anti-inflammatory compounds as taught by Rand as one would expect the device to perform equally well with the claimed formulation.

In regards to claims 51-53, the makeup of the medicament compound and all its components is considered to be a matter of obvious design choice as one of ordinary skill in the art at the time the invention was made would have expected the device to perform equally as well with the claimed medicament compound.

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-27, and 34-46 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 40 of U.S. Patent Publication No. 2005/0224525. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim the exact structural elements in the exact same claim language. However, the Publication 2005/0224525 is silent as to the device being used with a medicament which has a viscosity from 10-2000 mPa.s at 25 degrees C. However, because the publication has the same structure as the claimed device, the publication is capable of using a medicament with the claimed viscosity and furthermore, the type of medication used is considered to be an obvious matter of design choice.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The following documents are considered to be pertinent art: Ritsche et al. (6,527,144) is related to a fluid dispensing device with a single actuating lever, Andersson (2001/0013343) relates to a fluid dispensing device with multiple

actuating levers, and Stradella (7,353,971) relates to a fluid dispensing device with multiple actuating levers with a step..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to COLIN STUART whose telephone number is (571)270-7490. The examiner can normally be reached on M-F 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/COLIN STUART/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771